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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,075	10/05/2001	Riccardo D'Agostino	CM1894MMH	8475

7590

09/08/2004

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EXAMINER

SINGH, ARTI R

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,075

Applicant(s)

D'AGOSTINO ET AL.

Examiner

Ms. Arti Singh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment/Arguments

1. The Examiner has carefully considered Applicant's amendments and accompanying remarks filed on 06/08/2004. Amendment to claims 14 and 24 have been entered, and the pending claims at this time are claims 15-25. The rejections made under paragraphs 3 & 4 (Double Patenting Statutory) is also withdrawn, and a new ODP rejection follows. Applicant's traverses that the DP rejection is incorrect; this has been remedied by withdrawal from the Examiner on this rejection only and a new ODP rejection has been set forth below. All other rejections are maintained and repeated for Applicant's convenience.

The second traversal is that the motivation or some suggestion must be found within the reference in order for the Examiner to establish a prima facie case of obviousness. To this the Examiner contends that it is not necessary that the reference actually suggest, expressly or in so many words, the changes or improvements that Applicant has made. The test for combining the references is what the references, as a whole would have suggested to one of ordinary skill in the art, which was to formulate a coated composite, which is dimensionally stable and durable. See *In re Sheckler*, 168 USPQ 716 (CCPA 1971); *In re Mc Laughlin* 170 USPQ 209 (CCPA 1971); *In re Young* 159 USPQ 725 (CCPA 1968). The last traversal by Applicant is that of the thickness limitation that were either directly or indirectly amended. The Examiner has addressed this and incorporated this is to the rejection restated below and thus all rebuttals have been addressed. Despite these advances, the amendments are not found to patentably distinguish the claims over the prior art and do not overcome the art rejection made in the previous office action.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 15-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6649222. Although the conflicting claims are not identical, they are not patentably distinct from each other because they appear to be obvious variants of one another. The same process steps are used to make the same product (see *In re Ochai*).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15-17, and 19-25 are rejected under 35 USC 103 (a) as being unpatentable over USPN 4,632,842 issued to Karwoski et al.

6. Karwoski et al. disclose a variety of biomedical articles, having both flexible and hard surfaces such as vascular and prosthetic devices, shunts, catheters, etc. (column 4, lines 53-56). Additionally, at column 4, line 8 of the instant patent, it states that the tubes produced by their invention must resist radial collapse; therefore it must have some sort of strength and rigidity. Upon any of the aforesaid formed articles there is deposited a uniform coating

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or film of a fluoropolymer (column 4, lines 36-40), by means of a plasma glow discharge in the presence of fluorine containing gas (column 2, line 55). The preferred coatings of the invention have a water contact angle of greater than 120° (column 12, lines 1-24) and thus meet the limitations desired in claims 16, 17 and 25. With regard to the limitations sought in claim 22 and 23 where the article is formed prior to coating, this is exemplified in columns 6-8 where the steps are shown in formulating the tubes and then coating them. Karwoski et al. teach a hard surface substrate coated with a fluorocarbon coating/film having a water contact angle higher than 120°; and wherein the coating is obtained via plasma glow discharge in the presence of fluorine containing gas they also teach the discharge to be between 200-500 millitorr (column 11) and the discharge to have a density between 0 and a 1000 watts (column 10). The only aspect that appears to differ from Applicant's limitations in the independent claims are the teaching of pulsating the plasma discharge. However, the Examiner takes the position that these limitations are considered product by process limitations, and that the claimed product that is the "treated substrate" appears to be or is similar to that of the prior art although produced by a slightly different method. The burden is shifted to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (See *In re Marosi* 710 F. 2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Further, even though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from the product of the prior art, the claim is unpatentable even though the prior art was made by a different process. See *In re Thorpe*, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regards to the limitation of thickness the Examiner takes the position that a person having ordinary skill in the art at the time the invention was made would have found it obvious to have modified the thickness of the coating , motivated by the resoned expectation of making the composite of Karwoski flexible. Furthermore, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 4,632,842 issued to Karwoski et al. as applied to claims 15-17 and 19-25 above, and further in view of USPN 5,627,079 issued to Gardella, Jr. et al.

Karwoski et al teach what is set forth above but fail to explicitly teach the use of glass, metal or ceramics as their chosen substrate. Gardella, Jr. et al. disclose coating fibers, films and sheets consisting of either polymeric, ceramic , metallic or glass (column 8, lines 34) materials with a fluorocarbon coating (column 5, lines 22-45) used on a plethora of biomedical devices (column 6, lines 18-24). A person having ordinary skill in the art would have found it obvious at the time the invention was made to have employed the substrate of Gardella Jr. et al. namely, a glass, ceramic or metallic layers , as the substrate in the invention of Karwoski et al., motivated by the desire to formulate a coated composite which is dimensionally stable and durable.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. It should be noted that WO 97/42356 teaches all the product-by=process limitations required by Applicant's claims 15 and 24. A rejection could have been made however the Examiner feels that it would be redundant since the rejection set forth above is the best prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Arti Singh whose telephone number is 571-272-1483. The examiner can normally be reached on M-F 9-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ms. Arti Singh
Primary Examiner
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Ars 09/04/04